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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,162	07/03/2003	Harald Althaus	05552.1452	4536

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,162	ALTHAUS, HARALD	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-10 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 4-10 and 12-14 are pending.

2. In view of the amendment filed 4/14/06, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-9 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridomas DSM ACC2540 and DSM ACC2541 are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

It is noted that said hybridomas were deposited under the Budapest Treaty (page 3-4 of specification), an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridomas secreting said antibodies have been deposited under the Budapest Treaty and that the hybridomas will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808.

Applicants' arguments filed 4/14/06 have been fully considered but are not found persuasive.

Applicants' position is that Applicant has filed Microorganism Deposit Declaration under 37 C.F.R. § 1.808(a). Applicant notes that the specification discloses the date of deposit and name and address of the depository at the paragraph spanning pages 3-4.

In response, it is noted that the Declaration is defective because Accession Numbers DSM ACC2540 is stated twice. Consequently, it is not clear DSM ACC2540 corresponded to which cell cultures such as 98/84011 or 01-102/01.

5. Claims 12-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of the process of preparing the antibodies where antibodies were obtained by which "process known to the skilled worker from the hybrid cell clone selected *this way*" as set forth in claim 12.

The specification discloses only two monoclonal antibodies and binding fragment thereof that bind specifically to human carbohydrate deficient transferring consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1-4. The said monoclonal antibodies are produced by immunizing an animal with unglycosylated human transferrin (CDT) and selecting the antibodies that bind specifically to the peptide consisting of the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4. The specification discloses a process for preparing the antibody as claimed in claim 4 wherein the process comprises the steps of (1) immunizing a suitable experimental animal with unglycosylated transferring, (2) fusing the spleen cells of the immunized animal to myeloma cells to obtain antibody-producing hybrid cells, (3) screening and selecting a hybrid cell clone which produces an antibody whose binding according to the results of an epitope mapping takes place in the region of the following four segments of the carbohydrate deficient transferring sequences as set forth in SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4 and (4) isolating the antibody that binds to said four segments.

With the exception of the specific antibody and binding fragment thereof that binds specifically to human unglycosylated transferrin peptide consisting of the amino acid sequence of SEQ ID NO: 1-4, there is insufficient written description about the process step of obtaining antibodies by which "process known to the skilled worker from the hybrid cell clone selected this way". Further, the claim appears to be a translation from a foreign language.

With regard to the test kit, the content of the kit is not adequately described.

Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' arguments filed 4/14/06 have been fully considered but are not found persuasive.

Applicants' position is that Applicant was clearly in possession of the subject matter of claims 4-7, 10 and 12-14. Claims 1-3 and 11 have been canceled. The sequences to which the antibodies of the invention bind are disclosed in the specification at, for instance, claim 4 itself. Further, the specification demonstrates that antibodies that bind to these sequences surprisingly have the ability to bind carbohydrate deficient transferring in an aqueous solution.

In response, the arguments with respect to claims 4-7, 10, and 13-14 are moot since the rejection to said claims have been dropped. With respect to claim 12, it appears that claim 12 is a translation from a foreign language. Consequently, it is not clear which "process" and which "this way" known to the skilled worker from the hybrid cell clone is/are part of the claimed invention. With regard to the "test kit", the content of the kit is not adequately described.

6. The following new ground of rejection is necessitated by the amendment filed April 14, 2006.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 4-10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The particular antibody that binds to all *four* segments (1) to (4) in claims 4 and 12 is indefinite and ambiguous because the antibody in the dependent claims 5 and 6 where the binding takes place only in the region of *three* or *two* segments (1) to (4) of the carbohydrate deficient transferring sequence. Further, the region of SEQ ID NO: 1 to which the antibody binds has no common amino acids in the region of SEQ ID NO: 2, SEQ ID NO: 3 and/or SEQ ID NO: 4. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

12. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 23, 2006

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